

PEREGRINE PHARMACEUTICALS INC

FORM 8-K

(Current report filing)

Filed 09/09/08 for the Period Ending 09/09/08

Address	14282 FRANKLIN AVE TUSTIN, CA 92780
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**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**

Washington, DC 20549

FORM 8-K

CURRENT REPORT

**Pursuant to Section 13 or 15(d) of the
Securities Exchange Act of 1934**

Date of Report (Date of earliest event reported): **September 9, 2008**

PEREGRINE PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State of other jurisdiction
of incorporation)

0-17085
(Commission File Number)

95-3698422
(IRS Employer
Identification No.)

14282 Franklin Avenue, Tustin, California 92780
(Address of Principal Executive Offices)

Registrant's telephone number, including area code: **(714) 508-6000**

Not Applicable
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2 below):

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425).
 - Soliciting material pursuant to Rule 14A-12 under the Exchange Act (17 CFR 240.14a-12)
 - Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR.14d-2(b))
 - Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))
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ITEM 2.02 RESULTS OF OPERATIONS AND FINANCIAL CONDITION

On September 9, 2008, Peregrine Pharmaceuticals, Inc. issued a press release to report the Company's financial results for the first quarter ended July 31, 2008. A copy of the press release is attached to this current report on Form 8-K as Exhibit 99.1. No additional information is included in this Current Report on Form 8-K.

The information included in this Current Report on Form 8-K, including the exhibit hereto, shall not be deemed "filed" for purposes of, nor shall it be deemed incorporated by reference in, any filing under the Securities Act of 1933 or the Securities Exchange Act of 1934, except as expressly set forth by specific reference in such a filing.

ITEM 7.01 REGULATION FD DISCLOSURE

On September 9, 2008, at 11:30 a.m. EDT/8:30 a.m. PDT, the Company hosted a conference call to discuss its First Quarter FY 2009 financial results. The webcast of the conference call will be archived on the Company's website for approximately 30 days.

ITEM 9.01 FINANCIAL STATEMENTS AND EXHIBITS

- (c) Exhibits. The following material is filed as an exhibit to this Current Report on Form 8-K:

**Exhibit
Number**

99.1 Press Release issued September 9, 2008

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

PEREGRINE PHARMACEUTICALS, INC.

Date: September 9, 2008

By: /s/ Paul J. Lytle

Paul J. Lytle
Chief Financial Officer

EXHIBIT INDEX

**Exhibit
Number**

Description

99.1

Press Release issued September 9, 2008

PEREGRINE

Pharmaceuticals, Inc.

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PEREGRINE PHARMACEUTICALS REPORTS FINANCIAL RESULTS FOR THE FIRST QUARTER OF FISCAL YEAR 2009

--Advances Achieved in All Clinical Programs, With Three Bavituximab Phase II Cancer Trials Ongoing--

--Updated Initial Data from Bavituximab Plus Docetaxel Phase II Breast Cancer Trial

Shows at Least 9 of 14 Evaluable Patients Achieved a Partial Tumor Response--

--Company Begins Work under Contract with Defense Threat Reduction Agency Potentially Worth Up to \$44.4 Million--

TUSTIN, Calif., September 9, 2008 -- Peregrine Pharmaceuticals, Inc. (Nasdaq: PPHM) today announced financial results for the first quarter of fiscal year (FY) 2009 ended July 31, 2008. The company reported a consolidated net loss of \$5,086,000, or \$0.02 per basic and diluted share, compared to a consolidated net loss of \$4,656,000 or \$0.02 per basic and diluted share for the same prior year period. The increased net loss primarily reflects increased investments in research and development as the company advanced its clinical programs for bavituximab and Cotara®.

Total revenues for the current quarter were \$1,517,000 compared to \$1,625,000 for the comparable quarter last year and were primarily generated from services provided by Avid Bioservices, the company's wholly owned contract manufacturing subsidiary. Total revenues for the quarter also include the first government contract revenues generated by Peregrine's contract with the Defense Threat Reduction Agency (DTRA), potentially worth up to \$44.4 million over a period of up to five years to evaluate bavituximab for the prevention or treatment of viral hemorrhagic fever infections.

Total costs and expenses increased to \$6,677,000 in the first quarter of FY 2009 from \$6,513,000 in the same prior year quarter. The increase was primarily related to Peregrine's increased investment in research and development associated with the advancement of its three clinical programs for bavituximab and Cotara® for the treatment of solid tumors and hepatitis C virus (HCV) infection. Research and development expenses were \$4,068,000 in the first quarter of FY 2009, compared to \$3,624,000 in the first quarter of FY 2008. At July 31, 2008, the company had \$9,963,000 in cash and cash equivalents compared to \$15,130,000 at fiscal year end April 30, 2008. In addition, liquid assets, representing cash and receivables, were \$13,856,000 at July 31, 2008 as compared with \$15,735,000 at fiscal year end April 30, 2008.

"Among the most significant developments this past quarter was having patient enrollment underway in all three of the Phase II trials in our bavituximab cancer program and reporting encouraging positive data from the trial testing bavituximab in combination with docetaxel in advanced breast cancer patients," said Steven W. King, president and CEO of Peregrine. "The positive data from this trial showed that we had exceeded our pre-determined criteria for proceeding to the next stage of the trial, with half of patients demonstrating partial tumor responses. We are reporting today that we have now seen additional patients with tumor responses in this trial, with nine of the 14 evaluable patients having achieved a partial tumor response. During the quarter, we also reported data from a prior bavituximab cancer study and from our ongoing Cotara study in glioblastoma (GBM) patients at the prestigious ASCO meeting, building a promising foundation for future peer-reviewed presentations and publications from our clinical programs."

Mr. King continued, "Our bavituximab anti-viral program received a major validation during the quarter when we were awarded up to a five-year contract potentially worth up to \$44.4 million with the DTRA to evaluate bavituximab for the treatment of viral hemorrhagic fever infections. We are excited about this program, which is already well underway and which is providing us with an important source of non-dilutive cash to fund activities that we expect to be beneficial to all of our bavituximab programs."

Mr. King added, "Our Avid manufacturing subsidiary continued to expand its client base and achieved the distinction of being named the first U.S. preferred vendor for a proprietary cell line that provides important benefits to customers. Our Avid revenues this quarter were in-line with expectations, and based on our client backlog and preferred vendor status, we expect robust revenue growth from Avid over the remainder of the fiscal year."

Recent Highlights

Bavituximab Anti-Cancer Program

All three initial Phase II trials in the bavituximab cancer program are now underway:

- Reported positive early results from the first cohort of patients enrolled in a Phase II trial of bavituximab in combination with docetaxel in advanced breast cancer patients. Bavituximab achieved the pre-specified primary endpoint in stage 1 of this trial. Of 14 evaluable patients, at that time seven had achieved partial tumor responses by the first eight week evaluation time point and seven had stable disease at week eight according to RECIST criteria. None of the patients showed tumor progression during this period. Since these data were reported, another two patients have achieved partial tumor responses, for a total of nine patients. The regimen as well tolerated, with adverse events similar to those expected from chemotherapy alone.
- Initiated patient dosing in a Phase II trial of bavituximab in combination with carboplatin and paclitaxel in patients with advanced breast cancer.
- Initiated patient dosing in a Phase II trial of bavituximab in combination with carboplatin and paclitaxel in patients with non-small cell lung cancer.
- Presented positive data from a completed Phase I study of bavituximab in combination with chemotherapy in patients with advanced cancer at the 2008 ASCO Annual Meeting.

Bavituximab Anti-Viral Program

The company continued to advance its bavituximab anti-viral program and was awarded a major government contract to assess the potential of bavituximab in viral hemorrhagic fevers.

- Entered into a five-year contract potentially worth up to \$44.4 million with the Department of Defense's DTRA to evaluate bavituximab for the prevention and treatment of viral hemorrhagic fever infections.
- Continued to enroll and dose patients in an ongoing Phase I clinical trial of bavituximab in HCV patients co-infected with HIV.
- Reported two major studies that were published in the journal *Science*, which highlighted the key role of phosphatidylserine (PS) in viral infections. Peregrine's bavituximab is an anti-PS agent.
- Was awarded two patents granting Peregrine broad anti-viral method claims using a range of phosphatidylethanolamine (PE) binding agents, including PE-binding peptides attached to anti-viral agents as well as those conjugated to antibodies or other substances. These patents are a potentially valuable complement to other Peregrine anti-phospholipid programs.

Cotara® Brain Cancer Program :

Peregrine advanced the Cotara brain cancer program during the quarter.

- Presented data from the Cotara dosing and dosimetry study at the ASCO 2008 Annual Meeting showing that Cotara concentrates in the brain tumor rather than affecting healthy organs. This data confirms a key safety attribute of Cotara—its ability to precisely target tumors. All of the patients in the cohort presented have already surpassed the expected median survival time for relapsed GBM patients.
 - Continued to enroll and dose patients in the Phase II safety and efficacy trial and in the Phase I dosing and dosimetry trial in patients with GBM, the deadliest form of brain cancer.
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Other Developments

- Avid Bioservices became the first U.S. pre-approved contract manufacturer for licensees of the DSM Biologics and Crucell PER.C6® cell line, a proprietary high yield cell line with important advantages over other approaches.
- Received a Staff Determination letter from the Nasdaq Stock Market indicating that the company was not in compliance with the \$1.00 minimum bid price requirement for continued listing. On September 4, 2008, Peregrine attended an oral hearing with an independent Nasdaq Panel and Peregrine requested an additional 180 days to regain compliance, or until January 20, 2009. The final written decision from Nasdaq is expected within 30 days of the hearing date.

Conference Call

The company will host a conference call today, September 9, 2008 at 11:30 a.m. EDT/8:30 a.m. PDT to discuss its First Quarter FY 2009 financial results.

To listen to a live broadcast of the call over the Internet or to review the archived call, please visit: <http://www.peregrineinc.com>. The webcast will be archived on Peregrine's website for approximately 30 days.

To listen to the conference call via telephone, please call the following number approximately 10 minutes prior to the scheduled start time and request to join the Peregrine Pharmaceuticals call: (800) 860-2442. A telephonic replay of the conference call will be available starting approximately one hour after the conclusion of the call through September 16, 2008 by calling (877) 344-7529, passcode 382933#.

About Peregrine Pharmaceuticals

Peregrine Pharmaceuticals, Inc. is a biopharmaceutical company with a portfolio of innovative product candidates in clinical trials for the treatment of cancer and hepatitis C virus (HCV) infection. The company is pursuing three separate clinical programs in cancer and HCV infection with its lead product candidates bavituximab and Cotara®. Peregrine also has in-house manufacturing capabilities through its wholly owned subsidiary Avid Bioservices, Inc. (www.avidbio.com), which provides development and bio-manufacturing services for both Peregrine and outside customers. Additional information about Peregrine can be found at www.peregrineinc.com

Safe Harbor Statement: Statements in this press release which are not purely historical, including statements regarding Peregrine Pharmaceuticals' intentions, hopes, beliefs, expectations, representations, projections, plans or predictions of the future are forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. The forward-looking statements involve risks and uncertainties including, but not limited to the risk that the company may experience delays in clinical trial patient enrollment, the results of future clinical trials may not correlate with the results from prior clinical and preclinical studies, the risk that Avid's revenue growth may slow or decline, the risk that Avid may experience technical difficulties in processing customer orders which could delay delivery of products to customers and receipt of payment, the risk that one or more existing Avid customers terminates its contract prior to completion, the risk that the company does not receive all of its funding under the DTRA contract, the risk that future protocol submissions may not be approved and the risk that the company may not be able to monetize any of its assets. It is important to note that the company's actual results could differ materially from those in any such forward-looking statements. Factors that could cause actual results to differ materially include, but are not limited to, uncertainties associated with completing preclinical and clinical trials for our technologies; the early stage of product development; the significant costs to develop our products as all of our products are currently in development, preclinical studies or clinical trials; obtaining additional financing to support our operations and the development of our products; obtaining regulatory approval for our technologies; anticipated timing of regulatory filings and the potential success in gaining regulatory approval and complying with governmental regulations applicable to our business. Our business could be affected by a number of other factors, including the risk factors listed from time to time in the Company's SEC reports including, but not limited to, the annual report on Form 10-K for the year ended April 30, 2008. The company cautions investors not to place undue reliance on the forward-looking statements contained in this press release. Peregrine Pharmaceuticals, Inc. disclaims any obligation, and does not undertake to update or revise any forward-looking statements in this press release .

-financial tables to follow-

PEREGRINE PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS

	JULY 31, 2008	APRIL 30, 2008
	<i>Unaudited</i>	
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	\$ 9,963,000	\$ 15,130,000
Trade and other receivables	2,099,000	605,000
Government contract receivables	1,794,000	-
Inventories, net	4,628,000	2,900,000
Prepaid expenses and other current assets	<u>1,198,000</u>	<u>1,208,000</u>
Total current assets	19,682,000	19,843,000
PROPERTY:		
Leasehold improvements	669,000	669,000
Laboratory equipment	4,140,000	4,140,000
Furniture, fixtures and office equipment	<u>919,000</u>	<u>919,000</u>
	5,728,000	5,728,000
Less accumulated depreciation and amortization	<u>(3,803,000)</u>	<u>(3,670,000)</u>
Property, net	1,925,000	2,058,000
Other assets	<u>1,201,000</u>	<u>1,156,000</u>
TOTAL ASSETS	<u>\$ 22,808,000</u>	<u>\$ 23,057,000</u>

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PEREGRINE PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS (continued)

	JULY 31, 2008	APRIL 30, 2008
	<i>Unaudited</i>	
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Accounts payable	\$ 3,134,000	\$ 2,060,000
Accrued clinical trial site fees	305,000	237,000
Accrued legal and accounting fees	210,000	450,000
Accrued royalties and license fees	151,000	222,000
Accrued payroll and related costs	955,000	1,084,000
Capital lease obligation, current portion	22,000	22,000
Deferred revenue	4,021,000	2,196,000
Deferred government contract revenue	980,000	-
Customer deposits	1,898,000	838,000
Other current liabilities	<u>336,000</u>	<u>331,000</u>
Total current liabilities	12,012,000	7,440,000
Capital lease obligation, less current portion	16,000	22,000
Commitments and contingencies		
STOCKHOLDERS' EQUITY:		
Preferred stock-\$.001 par value; authorized 5,000,000 shares; non-voting; nil shares outstanding	-	-
Common stock-\$.001 par value; authorized 325,000,000 shares; outstanding – 226,210,617 and 226,210,617, respectively	226,000	226,000
Additional paid-in capital	246,476,000	246,205,000
Accumulated deficit	<u>(235,922,000)</u>	<u>(230,836,000)</u>
Total stockholders' equity	<u>10,780,000</u>	<u>15,595,000</u>
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	<u>\$ 22,808,000</u>	<u>\$ 23,057,000</u>

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PEREGRINE PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

	THREE MONTHS ENDED	
	July 31, 2008	July 31, 2007
	<i>Unaudited</i>	<i>Unaudited</i>
REVENUES:		
Contract manufacturing revenue	\$ 1,193,000	\$ 1,621,000
Government contract revenue	324,000	-
License revenue	-	4,000
Total revenues	<u>1,517,000</u>	<u>1,625,000</u>
COSTS AND EXPENSES:		
Cost of contract manufacturing	903,000	1,181,000
Research and development	4,068,000	3,624,000
Selling, general and administrative	1,706,000	1,708,000
Total costs and expenses	<u>6,677,000</u>	<u>6,513,000</u>
LOSS FROM OPERATIONS	<u>(5,160,000)</u>	<u>(4,888,000)</u>
OTHER INCOME (EXPENSE):		
Interest and other income	75,000	239,000
Interest and other expense	(1,000)	(7,000)
NET LOSS	<u>\$ (5,086,000)</u>	<u>\$ (4,656,000)</u>
WEIGHTED AVERAGE COMMON SHARES OUTSTANDING	<u>226,210,617</u>	<u>206,071,568</u>
BASIC AND DILUTED LOSS PER COMMON SHARE	<u>\$ (0.02)</u>	<u>\$ (0.02)</u>